

REMARKS

Applicants again wish to thank the Examiner for the courtesy of conducting a telephone interview with applicants' representative. During the interview, a number of claims were discussed, including Claims 1 and 11. The cited reference WO99/12524 was also discussed. Proposed claim amendments were also discussed.

Claims 1, 2, 4-11,15,and 18-25 are in this application. Claims 1 and 11 have been amended and Claims 18-25 have been added.

Support for the amendments to Claims 1 and 11 is found, *inter alia*, on page 8 and in the examples.

Support for new Claim 18 is found in Claim 1 and *inter alia* on page 8 and in the examples.

Support for new Claim 19 is found, *inter alia*, on pages 8-10 and the examples. Support for new Claims 20-24 is found in, *inter alia*, Example 10 and other examples. Support for new Claim 25 is found in the specification, *inter alia*, on page 8.

The Examiner cites WO 99/12524 and states that Claims 1, 2, 4-11 and 15 are obvious in view of this reference. As before, this is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP 706.02(j). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.

The reference cited by the Examiner do not set forth even a *prima facie* case of obviousness for the invention as claimed at least for the following reasons.

As explained above, Claims 1 and 11 have been amended to define the fast release layer and the extended release layer as single unit layers. In WO 99/12524 it is disclosed that the first and second fractions comprise multiple units (see the abstract, line 4; page 1, line 10-15; page 6, lines 10-12; and page 6, line 25-page 10.) A tablet of single unit layers is not obvious from a reference that discloses fractions that comprise multiple units such as pellets.

The formulation of multiple units into a single unit tablet, for example, a tablet of a fast release layer and an extended release layer, is not possible technically because the application of the force required to compress a tablet in a tablet compressing machine will lead to rupturing of the multiple units resulting in loss of uniformity thus producing variable and unpredictable release of the active ingredient, e.g. nimesulide. A natural consequence of this, is batch-to-batch variation. Therefore, it is clear that one skilled in the art considering this reference would not have a reasonable expectation that a controlled release pharmaceutical tablet composition of nimesulide made of single unit layers can be prepared.

Therefore, it is respectfully requested that the rejection be withdrawn.

Accordingly, it is submitted that the current application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



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